IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff,	
v.	
SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (LPS) **DEMAND FOR JURY TRIAL**
SAREPTA THERAPEUTICS, INC., Defendant and Counter-Plaintiff	[redacted]
v.	
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff, Counter-Defendants and Counterclaimants.	

COUNTER-DEFENDANTS' AMENDED ANSWER TO COUNTER-PLAINTIFF'S COUNTERCLAIMS AND NEW COUNTERCLAIMS

Counter-Defendants Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") and NS Pharma, Inc. ("NS Pharma") (collectively, "Counter-Defendants"), by their attorneys, answer the Counterclaims of Counter-Plaintiff Sarepta Therapeutics, Inc. ("Sarepta") as follows:

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING THE NATURE OF THE ACTION

1. Sarepta asserts counterclaims for infringement of U.S. Patent Nos. 9,994,851 ("the '851 patent") (Exhibit A); 10,227,590 ("the '590 patent") (Exhibit B); and 10,266,827 ("the '827 patent") (Exhibit C) (collectively, "the UWA Patents") arising under the patent laws of the United States, 35 U.S.C. § 1 et seq. These patent infringement claims arise out of Defendants' unauthorized manufacture, use, sale, offer for sale, and/or importation in the United States of Viltepso, also known as viltolarsen, and Defendants' intentional encouragement of physicians and patients to administer Viltepso.

ANSWER: Counter-Defendants admit that Sarepta's counterclaims purport to assert claims for infringement of the '851 Patent, the '590 Patent, and the '827 Patent. Counter-Defendants deny the remaining allegations in paragraph 1.

2. Sarepta further asserts a counterclaim for declaratory judgment of invalidity of U.S. Patent Nos. 9,708,361 ("the '361 patent"); 10,385,092 ("the '092 patent"); 10,407,461 ("the '461 patent"); 10,487,106 ("the '106 patent"); 10,647,741 ("the '741 patent"); 10,662,217 ("the '217 patent"); and 10,683,322 ("the '322 patent") (collectively, "the NS Patents") arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

ANSWER: Counter-Defendants admit that Sarepta's counterclaims purport to assert claims for declaratory judgment of invalidity of the '361 Patent, the '092 Patent, the '461 Patent, the '106 Patent, the '741 Patent, the '217 Patent, and the '322 Patent. Counter-Defendants deny the remaining allegations in paragraph 2.

3. Sarepta further asserts a counterclaim for breach of contract arising under Delaware state law.

ANSWER: Counter-Defendants admit that Sarepta's counterclaims purport to assert a claim for breach of contract arising under Delaware state law. Counter-Defendants deny the remaining allegations in paragraph 3.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING THE PARTIES

4. Sarepta is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 215 First Street, Cambridge, Massachusetts 02142.

ANSWER: On information and belief, admitted.

5. Nippon Shinyaku represents in its Second Amended Complaint that it is a Japanese company with a principal pace of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

ANSWER: Counter-Defendants admit the allegations in paragraph 5.

6. Nippon Shinyaku represents in its Second Amended Complaint that by virtue of a license agreement with NCNP, Nippon Shinyaku holds the exclusive assertion rights for the NS Patents.

ANSWER: Counter-Defendants admit the allegations in paragraph 6.

7. Upon information and belief, NS Pharma is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 149 East Ridgewood Ave., Suite 280S, Paramus, NJ 07652. Upon information and belief, NS Pharma is a wholly owned U.S. subsidiary of Nippon Shinyaku. Upon information and belief, NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso.

ANSWER: Counter-Defendants admit that NS Pharma is a corporation organized and existing under the laws of the State of Delaware. Counter-Defendants further admit that NS Pharma is a wholly-owned subsidiary of Nippon Shinyaku and that NS Pharma is Nippon Shinyaku's U.S. Agent authorized by FDA to market Viltepso. Counter-Defendants admit that NS Pharma has a principal place of business at 140 East Ridgewood Ave., Suite 280S, Paramus, NJ 07652. Counter-Defendants deny the remaining allegations in paragraph 7.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING JURISDICTION AND VENUE

8. There is an actual justiciable controversy between Defendants and Sarepta concerning Defendants' liability for infringement of the UWA Patents.

ANSWER: Counter-Defendants admit that an actual justiciable controversy exists between Counter-Defendants and Sarepta regarding Sarepta's allegations that Counter-Defendants infringe the UWA Patents. Counter-Defendants deny liability for infringement of the UWA Patents and deny the remaining allegations in paragraph 8.

9. Sarepta's counterclaims against Defendants for infringement of the UWA Patents arise under the patent laws of the United States, 35 U.S.C. § 1 et seq.

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims against Counter-Defendants for infringement of the UWA Patents arise under the patent laws of the United States, 35 U.S.C. § 1 et seq. Counter-Defendants deny the remaining allegations in paragraph 9.

10. This Court has subject matter jurisdiction over the patent infringement counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that the Court has subject matter jurisdiction over the patent infringement counterclaims under 28 U.S.C. §§ 1331 and 1338(a). Counter-Defendants deny any allegations of infringement of the UWA Patents and deny the remaining allegations in paragraph 10.

11. There is an actual justiciable controversy between Defendants and Sarepta concerning the invalidity of the NS Patents as evidenced by Nippon Shinyaku's allegations in the Second Amended Complaint concerning Sarepta's alleged liability for infringement of the NS Patents.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that there is an actual justiciable controversy between Counter-Defendants and Sarepta concerning the invalidity of the NS Patents as evidenced by Nippon Shinyaku's allegations in the Second Amended Complaint concerning Sarepta's liability for infringement of the NS Patents. Counter-Defendants deny the remaining allegations in paragraph 11.

12. Sarepta's counterclaim for declaratory judgment of invalidity of the NS Patents arises under the patent laws of the United States, 35 U.S.C. § 1 et seq. and under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaim for declaratory judgment of invalidity of the NS Patents arises under the patent laws of the United States, 35 U.S.C. § 1 et seq. and under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq. Counter-Defendants deny the remaining allegations in paragraph 12.

13. This Court has subject matter jurisdiction over the declaratory judgment counterclaim of invalidity of the NS Patents under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that this Court has subject matter

jurisdiction over the declaratory judgment counterclaim of invalidity of the NS Patents under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Counter-Defendants deny the remaining allegations in paragraph 13.

14. There is an actual justiciable controversy between Nippon Shinyaku and Sarepta concerning Nippon Shinyaku's breach of contract.

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim. Counter-Defendants deny the remaining allegations in paragraph 14.

15. Sarepta's breach of contract counterclaim arises under Delaware state law.

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim under Delaware law. Counter-Defendants deny the remaining allegations in paragraph 15.

16. This Court has subject matter jurisdiction over the breach of contract counterclaim under 28 U.S.C. §§ 1332(a) and 1367(a).

ANSWER: Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim. Counter-Defendants deny the remaining allegations in paragraph 16.

17. Personal jurisdiction is proper over Nippon Shinyaku at least because Nippon Shinyaku has commenced this action and thus submitted to this Court's personal jurisdiction.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that personal jurisdiction is proper over Nippon Shinyaku for purposes of this action only at least because Nippon Shinyaku has

commenced this action and thus submitted to this Court's personal jurisdiction. Counter-Defendants deny the remaining allegations in paragraph 17.

18. Upon information and belief, personal jurisdiction is proper over NS Pharma, a Delaware corporation, at least because it has committed acts of infringement of the UWA Patents in Delaware by offering to sell and selling Viltepso (viltolarsen) in the State of Delaware. In addition, upon information and belief, Nippon Shinyaku conferred with, and coordinated with, NS Pharma in bringing this action and thus NS Pharma has consented to this Court's personal jurisdiction.

ANSWER: Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that personal jurisdiction is proper over NS Pharma for purposes of this action only. Counter-Defendants deny the remaining allegations in paragraph 18.

19. Upon information and belief, Nippon Shinyaku directly or through its agents including its wholly owned U.S. subsidiary NS Pharma, manufactures, markets, offers to sell, sells, and/or distributes Viltepso (viltolarsen) in the State of Delaware and elsewhere in the United States, and Viltepso is prescribed by physicians practicing in Delaware and elsewhere in the United States, is available at pharmacies or medical facilities located within Delaware and elsewhere in the United States, and/or is used by patients in, and/or residents of, Delaware and elsewhere in the United States.

ANSWER: Counter-Defendants admit that Nippon Shinyaku directly or through its agents and other third parties manufactures, markets, offers to sell, sells, and/or distributes Viltepso (viltolarsen) in the United States. Counter-Defendants also admit that Viltepso is prescribed by physicians practicing in the United States, is available at pharmacies or medical facilities in the United States, and/or is used by patients in, and/or residents of, Delaware and elsewhere in the United States. Counter-Defendants deny the remaining allegations in paragraph 19.

20. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b).

ANSWER: Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that venue is proper in this Court for purposes of this action only. Counter-Defendants deny the remaining allegations in paragraph 20.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING THE UWA PATENTS

21. On June 12, 2018, the USPTO issued the '851 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '851 patent is assigned to the University of Western Australia. A copy of the '851 patent is attached hereto as Exhibit A. The '851 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '851 patent for the treatment of muscular dystrophies and the right to enforce the '851 patent.

ANSWER: Counter-Defendants admit that the '851 patent is entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" and states that it issued on June 12, 2018. Counter-Defendants further admit that the face of the '851 patent lists the Assignee as the University of Western Australia and that Sarepta's Exhibit A purports to be a copy of the '851 patent. Counter-Defendants deny that the '851 patent is valid and enforceable. Counter-Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 21 and therefore deny the same.

22. On March 12, 2019, the USPTO issued the '590 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '590 patent is assigned to the University of Western Australia. A copy of the '590 patent is attached hereto as Exhibit B. The '590 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '590 patent for the treatment of muscular dystrophies and the right to enforce the '590 patent.

ANSWER: Counter-Defendants admit that the '590 patent is entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" and states that it issued on March 12, 2019. Counter-Defendants further admit that the face of the '590 patent lists the Assignee as the University of Western Australia and that Sarepta's Exhibit B purports to be a copy of the '590 patent. Counter-Defendants deny that the '590 patent is valid and enforceable. Counter-Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 22 and therefore deny the same.

23. On April 23, 2019, the USPTO issued the '827 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '827 patent is assigned to the University of Western Australia. A copy of the '827 patent is attached hereto as Exhibit C. The '827 patent is fully maintained and is valid and enforceable. Sarepta has exclusive

rights to the '827 patent for the treatment of muscular dystrophies and the right to enforce the '827 patent.

ANSWER: Counter-Defendants admit that the '827 patent is entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" and states that it issued on April 23, 2019. Counter-Defendants further admit that the face of the '827 patent lists the Assignee as the University of Western Australia and that Sarepta's Exhibit C purports to be a copy of the '827 patent. Counter-Defendants deny that the '827 patent is valid and enforceable. Counter-Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 23 and therefore deny the same.

24. The UWA Patents are listed in the U.S. Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for New Drug Application ("NDA") No. 211970 for Sarepta's Vyondys 53® product, also known as golodirsen. Each of the UWA Patents covers, inter alia, an antisense oligonucleotide of 20 to 31 bases wherein a base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195 disclosed in the UWA Patents, in which uracil bases are thymine bases, and a method of using it for the treatment of Duchenne Muscular Dystrophy ("DMD") in patients who have a mutation of the DMD gene that is amenable to exon 53 skipping.

ANSWER: Counter-Defendants admit that the UWA Patents are listed in the U.S. Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for New Drug Application ("NDA") No. 211970 for Sarepta's Vyondys 53® product, also known as golodirsen. Counter-Defendants further admit that each of the claims in the UWA Patents claims, inter alia, an antisense oligonucleotide of 20 to 31 bases, wherein the base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195 in which uracil bases are thymine bases. Counter-Defendants further admit that the claims of the '827 patent claim a method for treating a patient with DMD in need thereof who has a mutation of the DMD gene that is amenable to exon 53 skipping. Counter-Defendants deny the remaining allegations in paragraph 24.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING DEFENDANTS' INFRINGING PRODUCT[1]

25. Upon information and belief, Defendants' product, Viltepso (viltolarsen), is a morpholino antisense oligonucleotide comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA. Viltepso (viltolarsen) Highlights of Prescribing Information (Aug. 2020), § 11; *see also* Viltepso (viltolarsen) Highlights of Prescribing Information (Mar. 2021). Viltepso contains 21 bases and CCTCCGGTTCTGAAGGTGTTC as the base sequence. Viltepso (viltolarsen) Highlights of Prescribing Information (Mar. 2021), § 11.

ANSWER: Counter-Defendants admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states "Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass." Counter-Defendants also admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states "Viltolarsen contains 21 linked subunits." Counter-Defendants further admit that the sequence of bases of Viltepso from the 5' end to the 3' end is CCTCCGGTTCTGAAGGTGTTC. Counter-Defendants deny the remaining allegations in paragraph 25.

26. Upon information and belief, Viltepso induces exon 53 skipping in a human dystrophin pre-mRNA. *Id.* § 12.1.

ANSWER: Counter-Defendants admit that § 12.1 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are

[1] Counter-Defendants have adopted the headings as provided in Sarepta's Counterclaims for ease of reference only. Counter-Defendants do not admit any allegation found in any of the headings and deny that their product is "infringing."

amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 26.

27. Upon information and belief, Viltepso is administered to DMD patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping and induces skipping of exon 53 of dystrophin pre-mRNA. *Id.* §§ 1, 12.1. Defendants' label for Viltepso has encouraged and continues to encourage such use.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping," and § 12.1 states "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 27.

28. Upon information and belief, Defendants conducted pre-clinical and clinical development of Viltepso (viltolarsen), including clinical trials, to generate data in support of their submission of an NDA with the FDA for Viltepso (viltolarsen).

ANSWER: Counter-Defendants admit that Nippon Shinyaku conducted pre-clinical and clinical development of Viltepso (viltolarsen), including clinical trials, to generate data in support of the submission of an NDA with the FDA for Viltepso (viltolarsen). Counter-Defendants deny that NS Pharma was involved in the pre-clinical development of Viltepso. Counter-Defendants deny the remaining allegations in paragraph 28.

29. Upon information and belief, on October 2, 2019, Nippon Shinyaku announced that it had submitted a rolling NDA for Viltepso (viltolarsen) with the FDA. Nippon Shinyaku News Release (Oct. 2, 2019).

ANSWER: Counter-Defendants admit that the article cited in Sarepta's counterclaims titled "U.S. FDA Submission of New Drug Application for NS-065/NCNP-01 (viltolarsen)" dated October 2, 2019 states that Nippon Shinyaku "announced that it has completed the submission of its rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for NS-065/NCNP-01 (viltolarsen)." Counter-Defendants deny the remaining allegations in paragraph 29.

30. On August 12, 2020, the FDA announced it had granted accelerated approval to Viltepso for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. FDA News Release (Aug. 12, 2020).

ANSWER: Counter-Defendants admit that the article cited in Sarepta's counterclaims titled "FDA Approves Targeted Treatment for Rare Duchenne Muscular Dystrophy Mutation" dated August 12, 2020 states that "[t]oday, the U.S. Food and Drug Administration granted accelerated approval to Viltepso (viltolarsen) injection for the treatment of Duchenne muscular dystrophy (DMD) in patients wo have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 30.

31. Upon information and belief, Nippon Shinyaku announced that NS Pharma, a wholly owned U.S. subsidiary of Nippon Shinyaku, had launched Viltepso for commercial sales in the United States as of August 19, 2020. Nippon Shinyaku News Release (Aug. 20, 2020). Upon information and belief, NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso. *Id*.

ANSWER: Counter-Defendants admit that the article cited in Sarepta's counterclaims titled "VILTEPSO™ (viltolarsen) injection Now Commercially Available in the U.S." dated August 20, 2020 states that "Nippon Shinyaku Co., Ltd. . . . announced today that NS Pharma, Inc. . . . a wholly owned subsidiary of Nippon Shinyaku made VILTEPSO™ (viltolarsen) now available for commercial sales in the United States market as of August 19 (EST)." Counter-Defendants further admit that NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso. Counter-Defendants deny the remaining allegations in paragraph 31.

32. Upon information and belief, since at least August 2020, Defendants have encouraged physicians to treat DMD patients by administering Viltepso to induce skipping of exon 53 of dystrophin pre-mRNA including through their labels for Viltepso. Defendants have also facilitated pricing and reimbursement of Viltepso in the United States.

ANSWER: Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. Counter-Defendants deny the remaining allegations in paragraph 32.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING DEFENDANTS' AWARENESS OF THE UWA PATENTS

33. Upon information and belief, Defendants have been familiar with and knew of the UWA Patents prior to this litigation. Upon information and belief, Defendants believed prior to this litigation that one or more claims of the UWA Patents covered Viltepso (viltolarsen). When the UWA Patents issued in 2018 and 2019, for example, Defendants' NDA seeking marketing approval for viltolarsen was under regulatory review in the United States. Upon information and belief, Defendants became aware of the UWA Patents after the UWA Patents were submitted for listing in the FDA Orange Book for Vyondys 53® in December 2019. Upon information and belief, Defendants expected that their Viltepso (viltolarsen) product, if approved, would compete directly with Sarepta's Vyondys 53® (golodirsen) product. Upon information and belief, Defendants learned of the UWA Patents through their efforts to research and/or monitor third-party U.S. patents that could potentially interfere with their ability to market Viltepso (viltolarsen) in the United States.

ANSWER: Counter-Defendants admit that they were aware of the UWA Patents by at least September 2019. Counter-Defendants further admit that the UWA Patents include claims aimed at capturing VILTEPSO. Counter-Defendants admit that the NDA seeking marketing approval for viltolarsen was under regulatory review in the United States in 2018 and 2019. Counter-Defendants further admit that Nippon Shinyaku and Sarepta are direct competitors in certain markets for antisense oligonucleotide-based therapies for the treatment of DMD. Counter-Defendants deny the remaining allegations in paragraph 33.

34. Sarepta and Nippon Shinyaku entered into a Mutual Confidentiality Agreement ("MCA") effective June 1, 2020. Upon information and belief, Defendants were already aware of

the UWA Patents when Sarepta and Nippon Shinyaku began business discussions under the MCA in June 2020.

ANSWER: Counter-Defendants admit that Sarepta and Nippon Shinyaku entered into a Mutual Confidentiality Agreement ("MCA") effective June 1, 2020. Counter-Defendants further admit that they were aware of the UWA Patents at least as of September 2019. Counter-Defendants deny the remaining allegations in paragraph 34.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM I (Infringement of the '851 Patent)

35. Sarepta realleges each of the foregoing Paragraphs 1-34 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-34 as if fully set forth herein.

36. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

37. Claim 1 of the '851 patent recites:

> An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

ANSWER: Counter-Defendants admit that paragraph 37 quotes claim 1 of the '851 patent.

38. Upon information and belief, Viltepso satisfies each element of at least claim 1 of the '851 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 38.

39. Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 11. Viltolarsen contains 21 linked subunits. *Id.* The base sequence of viltolarsen is CCTCCGGTTCTGAAGGTGTTC, which includes CTGAAGGTGTTC as 12 consecutive bases. *Id.*

ANSWER: Counter-Defendants admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states "Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass." Counter-Defendants also admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states "Viltolarsen contains 21 linked subunits." Counter-Defendants further admit that the sequence of bases of Viltepso from the 5' end to the 3' end is CCTCCGGTTCTGAAGGTGTTC. Counter-Defendants deny the remaining allegations in paragraph 39.

40. Viltepso is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. *Id.* § 12.1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 12.1 that "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 40.

41. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id.* § 1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the

treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 41.

42. Upon information and belief, Defendants have directly infringed and continue to directly infringe at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, by engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Viltepso in the United States in violation of 35 U.S.C. § 271(a).

ANSWER: Counter-Defendants deny the allegations in paragraph 42.

43. Upon information and belief, Defendants knew or should have known of the existence of the '851 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '851 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '851 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

ANSWER: Counter-Defendants admit that they were aware of the '851 Patent by at least September 2019. Counter-Defendants deny the remaining allegations in paragraph 43.

44. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1. Upon information and belief, Viltepso has no substantial non-infringing uses, and Defendants know that Viltepso is especially made or especially adapted for use in infringement of the '851 patent.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 44.

45. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id.* Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '851 patent.

ANSWER: Counter-Defendants admit that Viltepso is sold, offered for sale, and/or distributed in the United States and that its Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 45.

46. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Counter-Defendants deny the allegations in paragraph 46.

47. Upon information and belief, Defendants' infringement of the '851 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '851 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 47.

48. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations in paragraph 48.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM II (Infringement of the '590 Patent)

49. Sarepta realleges each of the foregoing Paragraphs 1-48 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-48 as if fully set forth herein.

50. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

51. Claim 1 of the '590 patent recites:

> An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

ANSWER: Counter-Defendants admit that paragraph 51 quotes claim 1 of the '590 patent.

52. Upon information and belief, Viltepso satisfies each element of at least claim 1 of the '590 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 52.

53. Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 11. Viltolarsen contains 21 linked subunits. *Id.* The base sequence of viltolarsen is CCTCCGGTTCTGAAGGTGTTC, which includes CTGAAGGTGTTC as 12 consecutive bases. *Id.*

ANSWER: Counter-Defendants admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states "Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass." Counter-Defendants also admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states "Viltolarsen contains 21 linked subunits." Counter-Defendants further admit that the sequence of bases of Viltepso from the 5' end to the 3' end is CCTCCGGTTCTGAAGGTGTTC. Counter-Defendants deny the remaining allegations in paragraph 53.

54. Viltepso is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. *Id.* § 12.1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 12.1 that "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 54.

55. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id.* § 1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 55.

56. Upon information and belief, Defendants have directly infringed and continue to directly infringe at least claim 1 of the '590 patent, either literally or under the doctrine of equivalents, by engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Viltepso in the United States in violation of 35 U.S.C. § 271(a).

ANSWER: Counter-Defendants deny the allegations in paragraph 56.

57. Upon information and belief, Defendants knew or should have known of the existence of the '590 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '590 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '590 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

ANSWER: Counter-Defendants admit that they were aware of the '590 Patent by at least September 2019. Counter-Defendants deny the remaining allegations in paragraph 57.

58. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso

(viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1. Upon information and belief, Viltepso has no substantial non-infringing uses, and Defendants know that Viltepso is especially made or especially adapted for use in infringement of the '590 patent.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 58.

59. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id.* Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '590 patent.

ANSWER: Counter-Defendants admit that Viltepso is sold, offered for sale, and/or distributed in the United States and that its Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 59.

60. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '590 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Counter-Defendants deny the allegations in paragraph 60.

61. Upon information and belief, Defendants' infringement of the '590 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '590 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 61.

62. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations in paragraph 62.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM III (Infringement of the '827 Patent)

63. Sarepta realleges each of the foregoing Paragraphs 1-62 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-62 as if fully set forth herein.

64. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

65. Claim 1 of the '827 patent recites:

> A method for treating a patient with Duchenne muscular dystrophy (DMD in need thereof who has a mutation of the DMD gene that is amenable to exon 53 skipping, comprising administering to the patient an antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

ANSWER: Counter-Defendants admit that paragraph 65 quotes claim 1 of the '827 patent.

66. Upon information and belief, the use of Viltepso satisfies each element of, and directly infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '827 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 66.

67. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 67.

68. Upon information and belief, Defendants knew or should have known of the existence of the '827 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '827 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '827 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

ANSWER: Counter-Defendants admit that they were aware of the '827 patent by at least September 2019. Counter-Defendants deny the remaining allegations in paragraph 68.

69. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id*. Upon information and belief, Viltepso has no substantial non-infringing uses, and Defendants know that Viltepso is especially made or especially adapted for use in infringement of the '827 patent.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 69.

70. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id.* Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '827 patent.

ANSWER: Counter-Defendants admit that Viltepso is sold, offered for sale, and/or distributed in the United States and that its Highlights of Prescribing Information with a revision

date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 70.

71. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '827 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Counter-Defendants deny the allegations in paragraph 71.

72. Upon information and belief, Defendants' infringement of the '827 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '827 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 72.

73. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations in paragraph 73.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM IV (Declaration of Invalidity of the NS Patents)

74. Sarepta realleges each of the foregoing Paragraphs 1-73 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-73 as if fully set forth herein.

75. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

76. Each claim of the NS Patents is invalid for failure to comply with one or more requirements of the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

ANSWER: Counter-Defendants deny the allegations in paragraph 76.

77. By way of example, the claims of the NS Patents are invalid under 35 U.S.C. §§ 102 and/or 103 in view of Popplewell, L.J., *Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human DMD Gene: Implications for Future Clinical Trials,* Neuromuscular Disorders 20:102–110 (2010) ("Popplewell") and Sazani, P., *Safety Pharmacology and Genotoxicity Evaluation of AVI-4658,* Int'l J. Toxicology 29(2):143–156 (2010) ("Sazani"), alone or in combination with other prior art, for at least the reasons set forth in Sarepta's IPR Petitions challenging the NS Patents. In granting Sarepta's IPR Petitions challenging all claims of all seven NS Patents, for example, the Patent Trial and Appeal Board found Sarepta's arguments and evidence of unpatentability persuasive, concluding in each institution decision that Sarepta "has demonstrated a reasonable likelihood of success in proving that the challenged claims of the [patent] are unpatentable." *See Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.,* Decisions Granting Institution in IPR2021-01134, Paper No. 20 (Jan. 12, 2022); IPR2021-01135, Paper No. 20 (Jan. 12, 2022); IPR2021-01136, Paper No. 19 (Jan. 13, 2022); IPR2021-01137, Paper No. 18 (Jan. 13, 2022); IPR2021-01138, Paper No. 18 (Jan. 13, 2022); IPR2021-01139, Paper No. 18 (Jan. 13, 2022); and IPR2021-01140, Paper No. 18 (Jan. 12, 2022).

ANSWER: Counter-Defendant admits that the Patent Trial and Appeal Board stated in the Institution Decisions for the IPR Petitions that Sarepta "has demonstrated a reasonable likelihood of success in proving that the challenged claims of the [patent] are unpatentable." Counter-Defendants deny the remaining allegations in paragraph 77.

78. An actual case or controversy exists between Sarepta and Defendants as to whether the claims of the NS Patents are invalid.

ANSWER: Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that there is an actual case or controversy between Counter-Defendants and Sarepta concerning the invalidity of the NS Patents. Counter-Defendants deny the remaining allegations in paragraph 78.

79. Sarepta is entitled to a declaratory judgment that the claims of the NS Patents are invalid.

ANSWER: Counter-Defendants deny the allegations of paragraph 79.

80. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations of paragraph 80.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM V (Breach of Contract)

81. Sarepta realleges each of the foregoing Paragraphs 1-80 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-80 as if fully set forth herein.

82. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

83. Sarepta asserts a claim for breach of contract arising under Delaware state law. This Court has subject matter jurisdiction over this breach of contract claim under 28 U.S.C. §§ 1332(a) and 1367(a).

ANSWER: Paragraph 83 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim arising under Delaware state law. Counter-Defendants deny the remaining allegations in paragraph 83.

84. This claim for breach of contract arises out of Nippon Shinyaku's material breach of the MCA with Sarepta.

ANSWER: Counter-Defendants deny the allegations in paragraph 84.

85. Properly interpreted, the MCA is a valid and enforceable contract between Sarepta and Nippon Shinyaku.

ANSWER: Counter-Defendants admit that the MCA is a valid and enforceable contract between Sarepta and Nippon Shinyaku. Counter-Defendants deny any remaining allegations in paragraph 85.

86. Sections 1-3 of the MCA define "Confidential Information" and proscribe improper disclosures or uses of confidential information beyond the permitted purposes. Section 2.2, entitled "Obligations of Confidentiality and Non-Use," states among other relevant provisions that:

> The Parties intend and agree that this Agreement, the Proposed Transaction and all disclosures, including all meetings, discussions, correspondence, communications, documents, or other materials exchanged between the Parties made in connection with this Agreement and the Proposed Transaction shall not be submitted, referenced, admitted or otherwise used by the Recipient, its Affiliates, or their respective Representatives against the other Party in any legal action, except in an action to enforce the terms of this Agreement, and shall be treated as conducted in the aid of negotiation and shall be governed by and entitled to the protections and privileges of Delaware Rule of Evidence 408 and Federal Rule of Evidence 408, as well as any and all analogous or applicable privileges or additional limitations on use and disclosure set forth herein. Furthermore, regardless of whether the Proposed Transaction leads to any arrangement or resolution of issues, the fact that these confidential Proposed Transactions occurred shall not be referenced in any legal action currently pending, including but not limited to the EP Oppositions, the JP Actions, or the Potential Actions. Neither Party nor their Affiliates or Representatives shall in any way attempt to place into evidence any document, fact, statement or opinion in any way relating to the Proposed Transaction for any purpose, regardless of whether such document, fact, statement or opinion would be admissible under FRE 408 or any other analogous or applicable privilege.

ANSWER: Counter-Defendants admit that paragraph 86 recites a portion of Section 2.2 of the MCA. Counter-Defendants further admit that the term "Confidential Information" is listed in Section 1 of the MCA along with a definition of the term. Counter-Defendants also admit that the title of Section 2 of the MCA recites "Obligations of Confidentiality and Non-Use." Counter-Defendants deny the remaining allegations of paragraph 86.

87. On July 14, 2021, Nippon Shinyaku filed its original Complaint in this action containing confidential information in violation of its agreement, materially breaching its obligations under the MCA, Sections 1-3.

ANSWER: Counter-Defendants admit that Nippon Shinyaku filed its Original Complaint in this action on July 13, 2021. Counter-Defendants deny the remaining allegations of paragraph 87.

88. Notwithstanding that in its first set of Rule 12 responsive motions Sarepta raised its objection to such confidential information appearing in Nippon Shinyaku's original Complaint contrary to the terms of the MCA, Nippon Shinyaku again included the same confidential material in its First Amended Complaint ("FAC"), filed September 10, 2021 (D.I. 39).

ANSWER: Counter-Defendants admit that Nippon Shinyaku filed its First Amended Complaint on September 10, 2021. Counter-Defendants further admit that on September 3, 2021, Sarepta filed a Motion to Dismiss and Motion to Strike certain paragraphs of the Original Complaint. Counter-Defendants deny the remaining allegations of paragraph 88.

89. Sarepta renewed its objection in subsequent Rule 12 responsive motions (D.I. 53, 54) to such confidential information appearing in Nippon Shinyaku's FAC contrary to the terms of the MCA.

ANSWER: Counter-Defendants admit that Sarepta filed a Motion to Dismiss and Motion to Strike Portions of the First Amended Complaint on September 24, 2021. Counter-Defendants deny the remaining allegations of paragraph 89.

90. On December 20, 2021, the Court found that Nippon Shinyaku had violated the confidentiality and non-use provisions of the MCA and struck from the FAC the second sentence of paragraph 2 as well as paragraphs 11, 78, and 91 of the FAC. (Hearing Tr. at 31-34; D.I. 84.)

ANSWER: Counter-Defendants admit that the Court struck the second sentence of paragraph 2 and paragraphs 11, 78, and 91 of the First Amended Complaint. Counter-Defendants deny the remaining allegations of paragraph 90.

91. As the Court found, Nippon Shinyaku "agreed not to hold the parties' confidential communications against Sarepta in future litigation" because the terms of the valid and enforceable MCA had prohibitions against mentioning confidential communications in legal actions. *Id.* at 32, 34. But Nippon Shinyaku materially breached the terms of the agreement by including confidential information in its original Complaint and again in its FAC, even after being put on notice of its breach, requiring further briefing, motions practice, and a ruling by this Court striking the confidential information from Nippon Shinyaku's pleading.

ANSWER: Counter-Defendants admit that in the Hearing Transcript from the hearing on December 20, 2021, the Court stated that "NS agreed not to hold the parties' confidential communications against Sarepta in future litigation." Counter-Defendants deny the remaining allegations of paragraph 91.

92. Sarepta has suffered prejudice and injury by virtue of Nippon Shinyaku's knowing and repeated bad-faith breaches of the MCA's confidentiality and non-use provisions of Section 2, entitling Sarepta to damages in an amount exceeding $75,000.

ANSWER: Counter-Defendants deny the allegations of paragraph 92.

93. In addition, in view of Nippon Shinyaku's knowing and repeated bad-faith breaches of the MCA, Nippon Shinyaku has unclean hands precluding enforcement of the MCA and depriving it of any entitlement to injunctive or other equitable relief for any alleged breach of the MCA by Sarepta.

ANSWER: Counter-Defendants deny the allegations of paragraph 93.

GENERAL DENIAL

Except as expressly admitted in the preceding paragraphs above, Counter-Defendants deny each and every allegation of Sarepta's Counterclaims including, without limitation, the headings and subheadings contained in the Counterclaims. Pursuant to Rule 8(b) of the Federal Rules of Civil Procedure, allegations contained in the Counterclaims to which no responsive pleading is required and allegations for which Counter-Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations shall be deemed denied. Counter-Defendants expressly reserve the right to amend and/or supplement their answer.

RESPONSE TO SAREPTA'S PRAYER FOR RELIEF

Counter-Defendants deny that Sarepta is entitled to the relief it requests or to any other relief.

RESPONSE TO SAREPTA'S DEMAND FOR A JURY TRIAL

Counter-Defendants admit that Sarepta has demanded a jury trial for all triable issues alleged in its counterclaims but denies that a jury trial is warranted for Counterclaim V.

DEFENSES

Without assuming any burden other than those imposed by operation of law, and without admitting that they bear the burden of proof with respect to any of the following, Counter-Defendants, on information and belief, while reserving the right to add additional defenses based on facts learned in discovery or otherwise assert the following defenses.

First Defense
(Non-Infringement of the UWA Patents)

Counter-Defendants have not infringed and will not infringe, directly or indirectly, any valid and enforceable claim of the UWA Patents, either literally or under the doctrine of equivalents.

Second Defense
(Invalidity of the UWA Patents)

Each asserted claim of the UWA Patents is invalid for failure to comply with one or more requirements of the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

Third Defense
(Prosecution History Estoppel and Disclaimer)

Sarepta's claims that Counter-Defendants infringe the UWA Patents are estopped in whole, or in part, by representations made or actions taken during the prosecution of the applications that lead to the UWA Patents and/or related patents under the doctrine of prosecution history estoppel and/or prosecution history disclaimer.

Fourth Defense
(No Invalidity of the NS Patents)

All claims of the NS Patents are not invalid or unenforceable under 35 U.S.C. § 1 *et seq.*, and Sarepta will not be able to demonstrate otherwise by clear and convincing evidence.

Fifth Defense
(No Breach of Contract)

Counter-Defendants have not breached any contractual obligations under the MCA. To the extent Sarepta asserts a breach of contract claim against Counter-Defendant NS Pharma, NS Pharma was not a party to the MCA.

Sixth Defense
(Failure to State a Claim)

Sarepta's Counterclaims fail to state a claim upon which relief may be granted.

Seventh Defense
(Equitable Defenses and Remedies)

Sarepta's breach of contract claim and/or requested remedies arising from said breach of contract claim are barred in whole or in part under principles of equity, including unclean hands. By way of example only, in light of Sarepta's breach of the MCA by filing its IPR Petitions before the PTAB instead of challenging the validity of the NS Patents in the District of Delaware, Sarepta has unclean hands precluding it from enforcing the MCA and depriving it of any entitlement to injunctive or equitable relief for any alleged breach of the MCA by Counter-Defendants.

Eighth Defense
(No Damages)

Sarepta has not incurred any damages resulting from its allegations that Counter-Defendants have infringed the UWA Patents and/or breached the MCA. Counter-Defendants deny any allegations of infringement of the UWA Patents and breach of the MCA.

Ninth Defense
(Limitation on Damages and Costs)

Sarepta's claims for relief are barred in whole or in part, including without limitation by 35 U.S.C. §§ 286, 287, and/or 288.

Tenth Defense
(No Willful Infringement of the UWA Patents)

Counter-Defendants have not willfully infringed the UWA Patents, and Sarepta is therefore not entitled to enhanced damages pursuant to 35 U.S.C. § 284.

Eleventh Defense
(Unenforceability of the UWA Patents Based on Inequitable Conduct)

As set forth in the Counterclaims below, the UWA Patents are unenforceable due to inequitable conduct.

Twelfth Defense
(No Exceptional Case)

Sarepta cannot prove that its case against Counter-Claim Defendants is exceptional and warrants the award of attorney fees under 35 U.S.C. § 285 or pursuant to the Court's inherent power.

Reservation of Additional Defenses

Counter-Defendants reserve the right to add additional defenses based on facts learned in discovery or otherwise.

COUNTERCLAIMS

Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (together, the "NS Counterclaimants") by and through their undersigned attorneys, assert the following allegations and counterclaims against Counterclaim Plaintiff Sarepta Therapeutics, Inc. ("Sarepta"):

Nature of the Action

1. The NS Counterclaimants assert a counterclaim for unenforceability of United States Patent Nos. 9,994,851 ("'851 Patent," D.I. 2-9), 10,227,590 ("'590 Patent," D.I. 2-10), and 10,266,827 ("'827 Patent," D.I. 2-11) (collectively, the "UWA Patents").

2. The NS Counterclaimants also assert a counterclaim for *Walker Process* fraud based on Sarepta's violations of the Sherman Act, 15 U.S.C. §§ 1 et seq. by asserting patents against the NS Counterclaimants that were obtained by fraud on the United States Patent and Trademark Office ("USPTO") in an effort to unlawfully acquire or maintain monopoly power through improper means. Upon information and belief, Sarepta is the exclusive licensee with assertion rights for the UWA Patents.

Parties

3. Nippon Shinyaku is a Japanese company with a principal place of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

4. NS Pharma is a Delaware corporation with its principal place of business at 149 East Ridgewood Ave., Suite 280S, Paramus, NJ 07652.

5. Nippon Shinyaku is an innovative pharmaceutical company whose mission is to "help people lead healthier, happier lives." It accomplishes this mission by developing and supplying unique and high-quality therapies that are safe and highly effective relative to other drugs and that contribute to a better quality of life for patients.

6. Nippon Shinyaku not only serves general patient populations through its various drugs for urological diseases, hematology, gynecology, and otorhinolaryngology—but it also seeks to provide meaningful relief for patients suffering from rare, intractable diseases like DMD.

7. NS Pharma is a wholly-owned subsidiary of Nippon Shinyaku, and markets VILTEPSO® in the United States.

8. Upon information and belief, Sarepta is a Delaware corporation with its principal place of business at 215 First Street, Cambridge, Massachusetts 02142.

Jurisdiction and Venue

9. The NS Counterclaimants' claims for declaratory judgment of unenforceability of the UWA Patents arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq. and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 et seq.

10. The NS Counterclaimants' *Walker Process* fraud claims arise under the Sherman Act, 15 U.S.C. §§ 1, et seq.

11. This Court has subject-matter jurisdiction over these claims under 28 U.S.C. §§ 1331 and 1338(a).

12. The amount in controversy exceeds $75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over Sarepta, a Delaware corporation, at least because Sarepta resides in this District and has consented to this Court's jurisdiction. D.I. 2-1, Section 10.

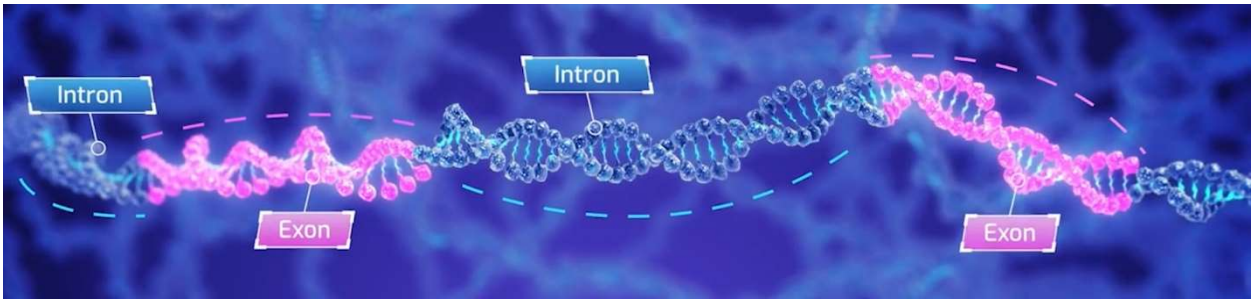
14. Venue is proper under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) at least because Sarepta, a Delaware corporation, resides in this District and because Sarepta has consented to this venue. D.I. 2-1, Section 10.

Duchenne Muscular Dystrophy

15. DMD is a severe X chromosome-linked genetic disorder that predominantly affects young boys. Approximately one in every 3,500 boys suffer from DMD, which is the most common form of hereditary progressive muscular dystrophy. Children with DMD suffer muscle weakness as early as age four and progressively lose muscle function and quality-of-life. By age twelve, DMD patients typically lose ambulatory function and are confined to wheelchairs. Body-wide muscle loss also contributes to numerous other health complications throughout patients' lives. As a result of DMD-induced cardiac and/or respiratory deficiencies, most patients suffering from DMD do not live past their twenties.

16. DMD is caused by mutation(s) in the dystrophin gene, which codes for the dystrophin protein. The dystrophin protein contributes to cell membrane stability in muscle cells and makes muscle cells less fragile. In DMD patients, however, the mutated dystrophin gene causes significant under-expression of the dystrophin protein, leaving them with insufficient levels of dystrophin protein to maintain their muscle cells.

17. The dystrophin gene is long, spanning approximately 2.2 million nucleotide pairs and comprising 79 exons (regions of nucleotides that code for the 3,685 amino acids making up the dystrophin protein) interspersed with introns (regions that do not code for the dystrophin protein).



18. In a non-DMD patient, cells generally prepare dystrophin protein from the gene as follows:

> **Transcription:** The dystrophin gene (DNA) is transcribed into an RNA strand containing both exons and introns known as "pre-mRNA."
>
> **Splicing:** Cellular machinery removes intron sequences and "splices" the exons together to form mRNA.
>
> **Translation:** Cellular machinery "reads" the mRNA strand three nucleotides at a time to determine and assemble the amino acid sequence for dystrophin.

19. DMD typically results when a mutation shifts the amino acid reading frame, producing a non-functional dystrophin protein. As show below, even a single nucleotide deletion can alter how the cellular machinery reads the remainder of the mRNA sequence (and consequently how the cell assembles the dystrophin protein).

> **Original:** ABC ABC ABC ABC ABC ABC
>
> **Mutation:** ABA BCA BCA BCA BCA BCA

20. Mutations that preserve the original amino acid reading frame may produce a partially functional dystrophin protein with exon deletions. This typically causes a less-severe condition known as Becker Muscular Dystrophy ("BMD"). Like DMD, BMD patients suffer from muscle weakness and atrophy, but they experience milder and slower disease progression. Many BMD patients do not experience symptoms of disease onset until they are well into adulthood.

21. There is no cure for DMD. Care providers have traditionally prescribed corticosteroids to promote muscle strength and delay disease progression. Such treatment carries substantial risks of side-effects, including weight gain and weakened bones, and does not stop the progress of the disease.

Exon-Skipping Antisense Oligomers as a Therapeutic Option

22. Antisense oligomers ("ASOs") are short nucleic acid strands that modify splice patterns to address the genetic defects responsible for DMD. ASOs bind with particular nucleotide sequences in or near the exon of interest on the pre-mRNA strand. ASOs interfere with the ordinary splicing process, causing the cell to "skip" the mutated exon(s) when preparing mRNA.

23. By "skipping" the mutated exons, ASOs cause cells to prepare shorter-than-normal mRNA while preserving the original amino acid reading frame. As a result, patients' cells produce partially functional—rather than non-functional—protein. Applied to DMD, these treatments effectively convert a DMD patient into a BMD patient, providing substantially better quality-of-life.

Nippon Shinyaku's Development of Exon 53 Skipping Oligomers

24. Recognizing the severe impact of DMD, Nippon Shinyaku began developing exon skipping therapies for DMD. Nippon Shinyaku focused first on therapies targeting exon 53, which would provide a treatment for approximately 8% of all DMD patients. Nippon Shinyaku ultimately determined that a 21 nucleobase (also call a 21mer) sequence targeted to the 36th to 56th nucleotides from the 5' end of exon 53 (H53_36-56) exhibited superior exon skipping.

25. On September 1, 2010, Nippon Shinyaku and National Center of Neurology and Psychiatry ("NCNP") filed Japanese Patent App. No. 2010-196032, which described their discoveries.

26. Nippon Shinyaku has since continued its development of the 21mer ASO—now known as VILTEPSO®—and secured approval in both Japan and the United States for the use of VILTEPSO® in treating DMD. While clinical trials are ongoing, initial results are promising. "[D]ystrophin levels increased, on average, from 0.6% of normal at baseline to 5.9% of normal at

week 25."[2] And VILTEPSO® patients did not experience kidney toxicity, a side effect the FDA reported for other ASOs. *Id.*

The UWA Patents

27. On June 12, 2018, the '851 Patent entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" issued to the University of Western Australia ("UWA") as assignees with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. On information and belief, Sarepta holds exclusive assertion rights of the '851 Patent.

28. On March 12, 2019, the '590 Patent entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" issued to UWA as assignees with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. On information and belief, Sarepta holds exclusive assertion rights of the '590 Patent.

29. On April 23, 2019, the '827 Patent entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" issued to the UWA as assignees with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. On information and belief, Sarepta holds exclusive assertion rights of the '827 Patent.

The NS Counterclaimants and Sarepta are Direct Competitors

30. The NS Counterclaimants and Sarepta are direct competitors that each provide antisense oligonucleotide-based therapies for the treatment of DMD. Sarepta and Nippon Shinyaku are the only companies with FDA clearance to market oligonucleotide therapies that are

[2] FOOD & DRUG ADMIN., *FDA Approves Targeted Treatment for Rare Duchenne Muscular Dystrophy Mutation*, (Aug. 12, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation (last accessed July 8, 2021).

indicated for the treatment of DMD for patients who have a mutation of the DMD gene that is amenable to exon 53 skipping. Sarepta's product is marketed under the name VYONDYS 53, and Nippon Shinyaku's product is marketed under the name VILTEPSO®. Sarepta also markets a product, EXONDYS 51, which is sometimes prescribed to DMD patients who have a mutation of the DMD gene that is amenable to exon 53 skipping.

31. In 2013 and 2015, the UWA obtained two patents directed towards antisense oligonucleotide-based therapies for the treatment of DMD: the '636 Patent (D.I. 39-1) and the '007 Patent) (D.I. 39-2). Each of these patents' claims encompasses Sarepta's VYONDYS 53 but fails to encompass Nippon Shinyaku's VILTEPSO®.

32. On January 16, 2017, FDA granted Orphan Drug Designation to Nippon Shinyaku for its antisense oligonucleotide-based therapy that would eventually be approved and marketed under the name VILTEPSO®. D.I. 39-3. Subsequent to FDA granting this Orphan Drug Designation, applications for the three UWA Patents were filed with the USPTO. These UWA Patents, unlike the '636 Patent and '007 Patent, included new claims aimed at capturing VILTEPSO®. Sarepta has listed the UWA Patents on its FDA Orange Book listing for VYONDYS 53®. NDA applicants "shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). In the Orange Book, Sarepta lists a patent expiry date for the UWA Patents of June 28, 2025 but is seeking a significant patent term extension that would extend their expiry date at least with respect to claims covering VYONDYS 53®.

33. Sarepta and Nippon Shinyaku have engaged in non-confidential communications regarding the licensing of Sarepta's UWA patents.

34. After some initial discussion, a meeting occurred on or about January 13, 2020, during which Sarepta's VYONDYS 53® product and Nippon Shinyaku's VILTEPSO® product were discussed. The meeting was attended by at least Mr. Matthew Gall of Sarepta and Mr. Masaya Toda of Nippon Shinyaku. As a result of that January 13, 2020, meeting, the Parties agreed to engage in negotiations concerning the Parties' patent portfolios, including Sarepta's UWA Patents. Sarepta requested that further discussions be held under a confidentiality agreement, and Nippon Shinyaku understood that these discussions would include discussions of licensing Sarepta's UWA Patents to avoid litigation.

35. During the same timeframe and before January 28, 2020, Chris Verni, Saretpa's Chief IP counsel sought out Nippon Shinyaku's outside counsel while they were attending a conference for the Association of Corporate Patent Counsel. Mr. Verni raised concerns about the possibility of litigation between the Parties and encouraged discussions as a means to avoid litigation.

36. After June 1, 2021 Sarepta and Nippon Shinyaku were no longer engaged in confidential discussions relating to their respective patent portfolios or products.

37. On July 6, 2021, Mr. Joe Zenkus, Senior Vice President at Sarepta, emailed Mr. Masaya Toda at Nippon Shinyaku. D.I. 39-4. In his email, Mr. Zenkus notes that "Sarepta is prepared to… ***pursue other actions deemed necessary for it to protect its rights***." Mr. Zenkus's statement was a threat that Sarepta would assert its UWA Patents against Nippon Shinyaku. This communication was not subject to any confidentiality obligation. Nippon Shinyaku's apprehension that Sarepta would file a lawsuit asserting the UWA Patents against Nippon

Shinyaku's U.S. sales of its VILTEPSO® product, threatening Nippon Shinyaku's goal to serving DMD patients and growing its U.S. market for this product, were realized when Sarepta asserted that the NS Counterclaimants infringe the UWA Patents. D.I. 89.

38. As set forth in Nippon Shinyaku's Second Amended Complaint (D.I. 86), the claims of the UWA Patents are invalid for failing to comply with the conditions and requirements of the patent laws of the United States, including, specifically and without limitation, 35 U.S.C. §§ 102, 103, and 112, and the rules, regulations, and laws pertaining thereto.

39. Discovery produced by Sarepta now confirms that the UWA Patents are unenforceable because they were obtained by fraud on the USPTO.

CLAIM X
(Unenforceability of the UWA Patents Based on Inequitable Conduct)

40. The NS Counterclaimants reallege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

Prosecution of the UWA Patents

41. Upon information and belief, [redacted]. Upon information and belief, Sarepta was responsible for the application and prosecution of the UWA Patents.

42. On September 14, 2017, the [redacted] and Sarepta, through their attorney [redacted], filed U.S. Patent Application No. 15/705,172 ("the '172 Application") on antisense molecules for inducing exon 53 skipping in the dystrophin gene, naming [redacted]. The '172 Application issued as the '851 Patent on June 12, 2018.

43. On August 24, 2018, UWA and Sarepta, through their attorney [redacted], filed U.S. Patent Application No. 16/112,371 ("the '371 Application") on antisense molecules for inducing exon 53 skipping in the dystrophin gene, again naming [redacted]. The '371 Application issued as the '590 Patent on March 12, 2019.

44. On August 24, 2018, UWA and Sarepta, through their attorney [redacted], filed U.S. Patent Application No. 16/112,453 ("the '453 Application") on methods for treating a patient with DMD with mutations amenable to exon 53 skipping by administering antisense molecules for inducing exon 53 skipping, again naming [redacted]. The '453 Application issued as the '827 Patent on April 23, 2019.

45. The '172 Application, the '371 Application, and the '453 Application (together, the "UWA Applications") each claimed priority to U.S. Patent Application No. 15/274,772, filed on September 23, 2016, which claimed priority to U.S. Patent Application No. 14/740,097, filed on June 15, 2015, which in turn claimed priority to U.S. Patent Application No. 13/741,150, filed on January 14, 2013, which in turn claimed priority to U.S. Patent Application No. 13/168,857, filed on June 24, 2011, which in turn claimed priority to U.S. Patent Application No. 12/837,359, filed on July 15, 2010, which in turn claimed priority to U.S. Patent Application No. 11/570,691, filed on January 15, 2008, which was the National Phase Application of PCT Application PCT/AU2005/000943, filed on June 28, 2005 ("the PCT Application"). The PCT Application claimed priority to Australian Patent Application No. 2004903474, filed on June 28, 2004 ("the AU Application").

46. The PCT Application was published as WO 2006/000057 ("WO '057"). The specifications of the UWA Applications are substantially identical to WO '057.

47. Sarepta asserts via its Counterclaims in this litigation that VILTEPSO® infringes at least claim 1 of the '851 Patent, at least claim 1 of the '590 Patent, and at least claim 1 of the '827 Patent ("the Sarepta Asserted Claims."). D.I. 89 ¶¶ 42, 46-47, 56, 59-61, 66, 70-71.

48. The Sarepta Asserted Claims each claim a genus of ASOs "of 20 to 31 bases comprising . . . at least 12 consecutive bases of [SEQ ID NO: 195] . . . where in the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping . . ." (the "Claimed Genus") and methods of using such ASOs for the treatment of DMD in patients who have a mutation of the DMD gene that is amenable to exon 53 skipping. *See* D.I. 89 ¶ 24.

49. Upon information and belief, none of the sequences presented in the AU Application target exon 53 or are described as being capable of inducing skipping of exon 53. SEQ ID NO. 195, a sequence recited in each of the Sarepta Asserted Claims, was not described by UWA until it filed the PCT Application. Accordingly, the earliest priority date to which the UWA Patents could possibly be entitled is June 28, 2005, the PCT Application filing date.

[redacted] ***Had Not Invented the Claimed Genus as of the PCT Filing Date***

50. As stated in WO '057 and the '851 Patent specification, as of June 28, 2005, [redacted] "attempts to induce exon skipping using antisense molecules have had mixed success" and "[s]imply directing the antisense oligonucleotides to motifs presumed to be critical for splicing is no guarantee of the efficacy of that compound in a therapeutic setting" and "[a]ttempts by the inventors to develop a rational approach in antisense molecules design were not completely successful as there did not appear to be a consistent trend that could be applied to all exons. As such, the identification of the most effective and therefore most therapeutic antisense molecules compounds has been the result of empirical studies." '851 patent, Col. 3:43-44; Col.

4:19-22; Col. 32:15-21; WO '057 at 4:13-14, 5:16-18, 35:1-6.[3] [redacted] further noted that "size or length of the antisense oligonucleotide itself is not always a primary factor when designing antisense molecules" and "there does not appear to be any standard motif that can be blocked or masked by antisense molecules to redirect splicing." '851 Patent, Col. 23:60-63 and 24:4-6; WO '057 at 21:10-13, 18-20.

51. During prosecution of the '172 Application, and in order to overcome rejections under 35 U.S.C. § 103, the applicant UWA, [redacted], and their attorney [redacted] argued that "at the time the instant invention was made, there was a significant level of unpredictability associated with selecting specific antisense oligonucleotide sequences to induce effective dystrophin exon skipping." *See* Exhibit A, 2018-01-05 Amendment, at 10. [redacted] and their attorney characterized the state of the art as teaching that "***significant experimentation is required*** to arrive at specific oligonucleotides" and "it is a hit-or-miss proposition in terms of whether any given antisense oligonucleotide will be capable of inducing exon skipping, ***even in situations where the antisense oligonucleotides are very similar to each other in terms of nucleotide sequence and other variables concerning the chemical backbone are fixed***." *Id.* at 11, 13 (emphasis original). In other words, [redacted] and their attorney were aware during prosecution of the UWA Patents and at the time the PCT Application was filed that providing a base sequence (SEQ ID NO: 195) and specifying a backbone (morpholino) is insufficient to predict whether any similar ASO will induce exon 53 skipping and relied on this unpredictability to overcome rejections.

[3] The Asserted Sarepta Patents have substantially identical specifications, which are in turn substantially identical to the PCT Application. For simplicity, the NS Counterclaimants cite to the '851 Patent specification and the WO '057 specification. However, the same disclosures may be found in the specifications of the '590 Patent and '827 Patent.

52. [redacted] and their attorney argued that, "at or near the date of Applicants' invention" in 2005 and even "beyond 2005," "***a trial and error procedure*** is still involved to identify potent AONs." *Id.* at 12-14 (emphasis original). [redacted] and their attorney also characterized a 2011 article by Wu et al. as "evidence developed after the instant filing date." *Id.* at 14. [redacted] and their attorney further argued that "[i]mportantly, the PTAB in Interference No. 106,007 concerning exon 53 antisense oligonucleotides for DMD held that the field of antisense oligonucleotides for exon skipping for DMD was unpredictable at the time the instant application was filed." *Id.* at 15. [redacted] and their attorney asserted that "[u]npredictability in this art was determined by the PTAB to have existed at the time of the instant invention (and years afterwards) and "[t]he PTAB's determination of unpredictability still applies." *Id.* at 16.

53. Upon information and belief, [redacted] The UWA Patents are only properly entitled to claim priority to, at the earliest, the September 14, 2017 filing date of the '172 Application.

54. The Claimed Genus encompasses a vast number of ASOs that are 20 to 31 bases and comprise at least 12 consecutive bases of SEQ ID NO: 195.

55. SEQ ID NO: 195 is not a morpholino ASO but rather a 2-O-methyl phosphorothioate ASO. *See, e.g.*, '851 Patent Table 1A titled "Description of 2-O-methyl phosphorothioate antisense oligonucleotides ***that have been used to date*** to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since ***these 2'-O-methyl antisense***

oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as 'T' and disclose SEQ ID NO: 195 as "CUG AAG GUGU UC UUG UAC UUC AUC C."(emphasis added); *see also* WO '057 at 16-17. The '851 Patent does not disclose any therapeutic utility or potential for therapeutic utility for SEQ ID NO: 195. Instead, the '851 Patent teaches that a ***different*** ASO that is ***not*** a member of the Claimed Genus, SEQ ID NO: 193, induced the strongest exon 53 skipping. '851 Patent, Col. 64:48-49; WO '057 at 62:14-15.

56. Upon information and belief, as of the PCT Application filing date, [redacted]

57. Upon information and belief, [redacted]

58. Thus, upon information and belief, as of the PCT Application filing date, [redacted]

59. [redacted]

[redacted]

60. Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies Inc*., 802 F. 2d 1367, 1376 (Fed. Cir. 1986). There must be a contemporaneous recognition and appreciation of the invention for there to be conception. *Silvestri v. Grant*, 496 F.2d 593, 596 (CCPA 1974).

61. Upon information and belief, [redacted] did not conceive the genus of antisense oligonucleotides claimed by each UWA Patent as of the PCT Application filing date. [redacted] could not possibly have formed a "definite and permanent idea of the complete and operative invention" or have a contemporaneous recognition and appreciation of the Claimed Genus [redacted].

62. [redacted] *Yorkey v. Diab*, 601 F.3d 1279, 1286 (Fed. Cir. 2010); *In re Curtis*, 354 F.3d 1347, 1358 (Fed. Cir. 2004) ("[A] patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when . . . the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.").

63. [redacted] cannot rely on a constructive reduction to practice because the disclosure of the PCT Application does not comply with 35 U.S.C. § 112, first paragraph. *Kawai v. Metlesics*, 480 F.2d 880, 886, (CCPA 1973). The UWA Patents are not entitled to claim priority to the June 28, 2005 filing date of the PCT Application under 35 U.S.C. § 120, and are invalid under 35 U.S.C. § 112 on the same basis. *See* D.I. 89 at ¶¶ 88-91.

64. [redacted]

65. The PCT Application references a single ASO with at least 12 consecutive bases of SEQ ID NO: 195, which only induced "very faint skipping to 50 nM." '851 patent, Table 39; WO '057 at 62. This single ASO neither enables nor describes the vast genus of ASOs encompassed by the Claimed Genus sufficient to meet the requirements of 35 U.S.C. § 112, particularly in an unpredictable art. *See Goeddel v. Sugano*, 61 F.3d 1350, 1355 (Fed. Cir. 2010).

66. The PCT Application does not disclose any ASO that is 20 to 31 bases in length and is at least 12 consecutive bases of SEQ ID NO: 195 other than SEQ ID NO: 195 itself.

67. The PCT Application does not disclose any ASO that is 20 to 31 bases in length and is "at least 12 consecutive bases of . . . (SEQ ID NO: 195), in which uracil bases are thymine bases" that induces exon 53 skipping.

68. The PCT Application does not disclose any ASO that is 20 to 31 bases in length and is at least 12 consecutive bases of SEQ ID NO: 195 and is a morpholino ASO that induces exon 53 skipping.

69. The PCT Application does not disclose even a single ASO with at least 12 consecutive bases of SEQ ID NO: 195 that induces more than "very faint skipping to 50 nM" of exon 53.

70. The PCT Application does not disclose any ASO in the Claimed Genus that induces a degree of exon 53 skipping that would be clinically or therapeutically relevant in treating a patent with DMD who has a mutation of the DMD gene that is amenable to exon 53 skipping.

71. In sum, the PCT Application does not constitute a "full, clear, concise and exact description" of the Claimed Genus. *In re Wertheim,* 646 F.2d 527, 538-539 (CCPA 1981). There are no "blaze marks within the disclosure that guide attention to the claimed species" or the Claimed Genus. *In re Ruschig*, 379 F.2d 990, 994-95 (CCPA 1967). Upon information and belief, no reasonable person of ordinary skill in the art would conclude from the PCT Application that [redacted] had invented and possessed the full scope of the Claimed Genus by its filing date.

72. Further demonstrating a lack of conception, recognition, or appreciation of the Claimed Genus when the PCT Application was filed, in work done *after* the filing date, [redacted] pursued SEQ ID NO: 193 rather than the Claimed Genus, as well as AONs targeting different exons. For example, in a later PCT application published as WO 2011/057350, [redacted] disclosed numerous ASOs targeting other exons, and only a handful of ASOs with at least 12 consecutive bases of SEQ ID NO: 195.

[redacted] ***and the Attorneys Knowingly Submitted a False Claim of Priority***

73. T[redacted] attorneys involved in the prosecution of the UWA Applications, including [redacted] (the "Attorneys"), and individuals at Sarepta involved in the filing or prosecution of the UWA Applications, understood that the field of ASOs for inducing exon skipping was highly

unpredictable both at the time of filing of the PCT Application and the filing dates of the UWA Applications.

74. Upon information and belief, [redacted] knew [redacted] had not invented the Claimed Genus by the PCT Application filing date. Upon information and belief, the Attorneys, [redacted], and individuals at UWA and Sarepta who were involved in the preparation or prosecution of the UWA Applications, knew that [redacted] had not invented the claimed genus by the PCT Application filing date. Upon information and belief, [redacted] and the Attorneys, and individuals at Sarepta who were involved in the preparation or prosecution of the UWA Applications knew that the claims set forth in the UWA Applications were not entitled to claim priority to the PCT Application because the requirements of 35 U.S.C. § 120 were not met. Yet, [redacted] the Attorneys, and individuals at Sarepta who were involved in the preparation or prosecution of the UWA Applications nevertheless submitted a claim of priority to the PCT Application in each of the UWA Applications. [redacted] Attorneys perpetuated this fraud by mischaracterizing the "time the instant invention was made," "the date of Applicants' invention" and "the time of the instant invention" to the USPTO in arguing for patentability. Exhibit A, at 10, 12, 16.

75. Thus, [redacted] and the Attorneys knew one fact and presented another, thereby permitting an inherence that they made the false representations with the intent to deceive. *See Dippin Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007).

76. These priority claims were false and objectively unreasonable. Upon information and belief, UWA, [redacted], and the Attorneys made the false priority claim in each of the UWA Applications at Sarepta's direction to avoid prior art and obtain patent claims that were aimed at capturing VILETPSO® and many other ASOs for anticompetitive purposes.

77. "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned." 37 C.F.R. § 1.56(a) (Sept. 8, 2000). Information is "material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability." 37 C.F.R. § 156(b). The priority date of a patent application is inherently material to patentability. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1233 (Fed. Cir. 2007).

78. Individuals who owe the USPTO a duty of candor and good faith are: "(1) each inventor named in the application; (2) each attorney or agent who prepares or prosecutes the application; and (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 156I.

79. Thus, [redacted] and the Attorneys, along with any individuals at Sarepta involved in the filing and prosecution of the UWA Applications, owe a duty of candor and good faith to the USPTO as individuals associated with the filing and prosecution of a patent application. 37 C.F.R. § 1.56I.

80. Upon information and belief, [redacted] and the Attorneys, along with any individuals at Sarepta involved in the filing and prosecution of the UWA Applications, each

violated their duty of candor and good faith to the USPTO by submitting and maintaining in each of the UWA Applications a claim of priority to the PCT Application that they knew was false and unsupported in view of [redacted] work and the specification.

81. Upon information and belief, [redacted] and the Attorneys, along with any individuals at Sarepta involved in the filing and prosecution of the UWA Applications, each violated their duty of candor and good faith to the USPTO by withholding information that [redacted] possessed at best [redacted] from the Claimed Genus as of the PCT Application filing date.

82. Upon information and belief, [redacted] and the Attorneys, along with any at Sarepta involved in the filing and prosecution of the UWA Applications, deliberately submitted false information and withheld information material to patentability with deceptive intent to obtain allowance of the Sarepta Asserted Claims. Upon information and belief, [redacted] and the Attorneys engaged in this conduct at Sarepta's direction in an attempt to obtain claims encompassing the NS Counterclaim Defendants' competing product [redacted].

83. Further, upon information and belief, [redacted] and the Attorneys, along with any individuals at Sarepta involved in the filing and prosecution of the UWA Applications, were aware of references published after the filing date of the PCT Application and before the filing dates of the UWA Applications that would have been material to patentability if they had been considered by the USPTO during examination of the UWA Applications.

84. By way of example only, on information and belief, [redacted] and the Attorneys, and individuals at Sarepta involved in the prosecution of the UWA Applications were

aware of Sazani et al., U.S. Patent Application Publication No. 2010/0130591 ("Sazani") and Watanabe et al., U.S. Patent Application Publication No. US 2013/0211062 ("Watanabe") (together, the "Material References"). Upon information and belief, [redacted] or the Attorneys knew these Material References were properly prior art to the UWA Applications but for the false priority claim. Upon information and belief, [redacted] and the Attorneys, and individuals at Sarepta involved in the prosecution of the UWA Applications were aware that the Material References were but-for material to the patentability of the Sarepta Asserted Claims.

85. Sazani is titled "Multiple Exon Skipping Compositions for DMD" and, for example, discloses an antisense oligomer spanning exactly H53A(+23+47), and is therefore identical to SEQ ID NO: 195 recited in the Sarepta Asserted Claims:

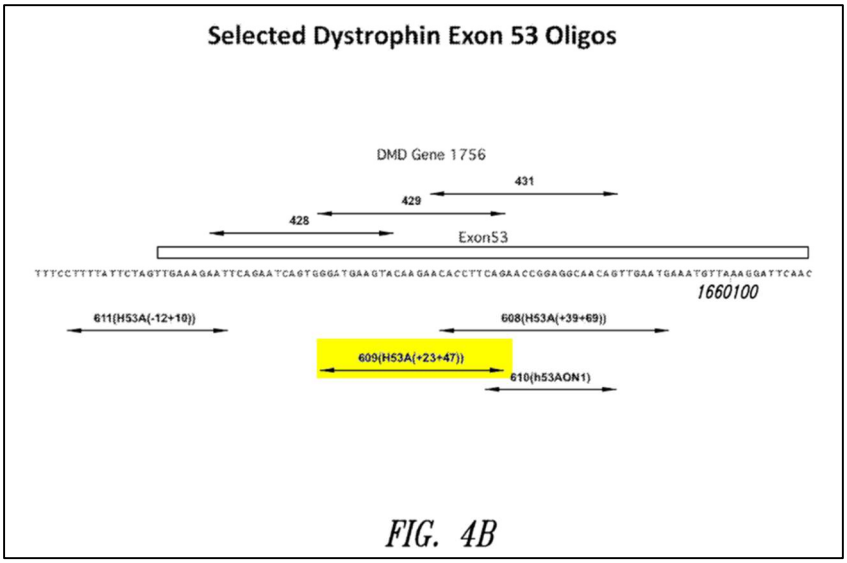
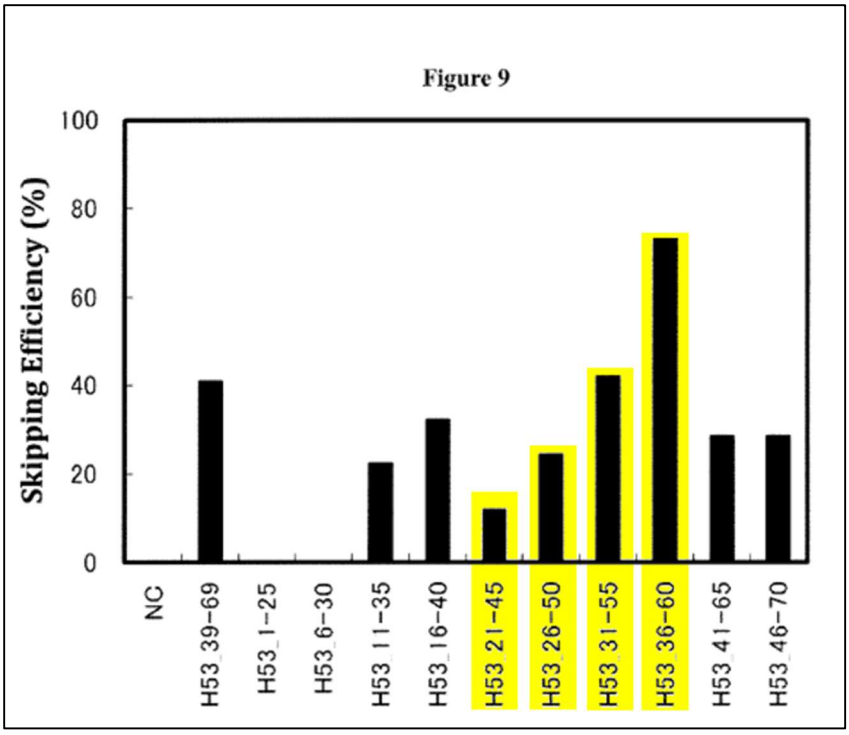


FIG. 4B

Watanabe, a patent publication disclosing AONs that cause exon 53 skipping, further discloses a series of antisense oligonucleotides that bind along exon 53 at sites that overlap with the portion of exon 53 to which SEQ ID NO: 195 binds and which cause varying degrees of skipping:



86. Sarepta filed the application published as Sazani. Upon information and belief, [redacted]. Sazani discloses that its SEQ ID NO: 429 "proved identical to H53A(+23+47) which is listed as SEQ ID NO: 195 in WO 2006/00057," the publication of the PCT Application. Sazani at [0293]. In contrast to the PCT Application, Sazani discloses its SEQ ID NO: 429 "was shown to be most effective at inducing exon skipping" from the ASOs targeting exon 53 described in Sazani, thus illustrating the unpredictability of the art. *Id.*

87. Upon information and belief, the claim of priority to the PCT Application caused the USPTO to allow the UWA Patents to issue. The USPTO did not consider the Material References because each was published after the claimed priority date and thus was not considered prior art under 35 U.S.C. §§ 102 and 103 to the PCT Application. The USPTO would not have allowed the UWA Patents to issue had the Examiner considered the Material References. Had the

Examiner considered the Material References, the Examiner would have found all claims of the UWA Patents unpatentable under 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious.

88. The single most reasonable inference able to be drawn from the evidence is that at least [redacted] and the Attorneys, as well as individuals from UWA or Sarepta involved in the prosecution of the UWA Applications, intended to deceive the USPTO by intentionally and falsely claiming priority to the PCT Application.

89. For example, Watanabe and other references from the Watanabe patent family have been cited against Sarepta's patent applications, including U.S. Application No. 16/243,926 ("the Sazani CON"), a continuation of Sazani that attempted to claim a genus of ASOs "of 21 bases comprising a base sequence . . . . where in the base sequence comprises 19 consecutive bases of SEQ ID NO: 431, where in the antisense oligonucleotide is a morpholino oligomer, and wherein the antisense oligonucleotide induces exon 53 skipping . . ." During prosecution of the Sazani CON, the USPTO examiner rejected a priority claim to the Sazani filing date for failure to comply with 35 U.S.C. § 112(a), thereby rendering Watanabe prior art to the Sazani CON. The USPTO examiner then rejected the claims as anticipated by Watanabe because Watanabe disclosed a sequence consisting of 21 bases comprising 19 consecutive bases of SEQ ID NO: 431. 2019-05-05 Final Rejection. Rather than arguing against the rejection or the priority date determination, Sarepta abandoned the Sazani CON. [redacted] one of the Attorneys, prosecuted the Sazani CON.

90. Upon information and belief, the rejection of the Sazani CON demonstrates that individuals at Sarepta were aware of Watanabe and that Watanabe was but-for material to the UWA Patents and was further aware that the priority claim to the PCT Application was legally unjustified.

91. As a result of [redacted] and the Attorneys' intentional false claim of priority to the PCT Application with the intent to deceive the USPTO, [redacted] and the Attorneys committed inequitable conduct, thereby rendering the UWA Patents unenforceable. Upon information and belief other individuals involved in the prosecution of the UWA Patents, such as individuals at UWA or Sarepta, also committed inequitable conduct rendering the UWA Patents unenforceable.

92. This case is exceptional, and the NS Counterclaimants are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

CLAIM XI
(Walker Process Fraud, 15 U.S.C. § 2)

93. The NS Counterclaimants reallege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

94. During prosecution of the UWA Applications, [redacted] and the Attorneys withheld and failed to disclose information concerning the lack of conception and reduction to practice of the Claimed Genus as of the PCT Application date. Upon information and belief, [redacted] and the Attorneys knowingly submitted a false claim of priority in each of the UWA Applications.

95. Upon information and belief, had the UWA Applications been accorded the priority date to which they were rightfully entitled, which was at the earliest, the September 14, 2017 filing date of the '172 Application, the UWA Patents would never have issued in view of the material references, which were never considered by the USPTO due to the false claim of priority.

96. As a result, the UWA Patents were obtained by fraud. Upon information and belief, there was an agency relationship as defined in section 2752 of the Manual of Patent Examining Procedure between UWA as the owner of the UWA Patents and Sarepta as the marketing applicant

before the FDA during the regulatory review period for Sarepta's VYONDYS 53 product, which began on January 28, 2006 and ended December 12, 2019. Upon information and belief, Sarepta was responsible for obtaining and maintaining the UWA Patents and is responsible for enforcing the Sarepta Asserted Claims against the NS Counterclaimants, all with knowledge of the fraudulent manner in which the UWA Patents were procured.

97. For example, [redacted]

98. Yet, Sarepta continues to maintain its patent infringement claims against the NS Counterclaimants based on the UWA Patents.

99. Section 2 of the Sherman Act prohibits monopolization and attempted monopolization. 15 U.S.C. § 2. By attempting to enforce the legal monopoly conferred by the UWA Patents, which were obtained by fraud, Sarepta has engaged in monopolization and/or attempted monopolization in violation of the Sherman Act, including within the doctrine set forth in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

100. Sarepta has engaged in predatory or anticompetitive conduct with a specific intent to monopolize by attempting to enforce the UWA Patents against its only competitor in the market for DMD patients with mutations amenable to exon 53 skipping who have been prescribed with an ASO therapy (the "Product Market"), Nippon Shinyaku.

101. No substitute FDA-approved therapies exist that have the same, or reasonably similar, clinical potential for treating DMD patients with mutations amenable to exon 53 skipping as ASO therapies.

102. There are no other FDA approved alternative therapies for treating DMD that are reasonable substitutes for ASO therapies. Exon-skipping therapies aim to address the underlying issue in DMD—insufficient levels of the protein dystrophin caused by mutation in the dystrophin gene. They use ASOs to alter RNA splicing, resulting in production of truncated dystrophin protein. Other FDA-approved therapies for DMD, such as corticosteroids, are mainly prescribed for symptom management and do not restore dystrophin levels.

103. By virtue of Sarepta's attempt to enforce the fraudulently obtained UWA Patents against the NS Counterclaimants, Sarepta has attempted to acquire illegal monopoly power in the Product Market.

104. The relevant geographic market for the Product Market is the United States. The United States is the relevant geographic area in which consumers in the Product Market rationally look for DMD treatment therapies. DMD treatment therapies are heavily regulated by the FDA, and the Federal Food, Drug, and Cosmetic Act prohibits importation of drugs that have not been approved by the FDA.

105. There is a dangerous probability that Sarepta will achieve monopoly power in the Product Market in the U.S. Upon information and belief, [redacted]

[redacted] Other than Sarepta's two products EXONDYS 51 and VYONDYS 53, the only other FDA-approved product in the Product Market is Nippon Shinkayu's VILTEPSO® product.

106. As a result of Sarepta's unlawful acts, the NS Counterclaimants have suffered and will continue to suffer antitrust injury. The antitrust injury to the NS Counterclaimants caused by Sarepta's refusal to grant a covenant not to sue and attempted enforcement of the UWA Patents against them include at least forcing the NS Counterclaimants to expend substantial amounts of money, time, and human resources in order to defend against Sarepta's claims of infringement.

107. By asserting the UWA Patents and continuing to assert them against the NS Counterclaimants despite fraudulently obtaining and enforcing those patents under *Walker Process*, Sarepta has abused the legal process, making the attorneys' fees incurred by the NS Defendants during that legal process a relevant antitrust injury. *TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1312 (Fed. Cir. 2016).

108. Faced with Sarepta's anticompetitive infringement claims and threats thereof, Nippon Shinyaku had three options: cease competition, take a license, or defend the infringement claims. If Nippon Shinyaku ceased competition, Sarepta would achieve a monopoly over the Product Market in the U.S. and critically ill DMD patients would be harmed from being deprived of a safe and effective therapy.

109. If Nippon Shinyaku took a royalty-bearing license, particularly one at a supracompetitive royalty rate, it would be placed in a disadvantageous competitive position. A royalty would raise the NS Counterclaimants' costs for VILTEPSO®. VILTEPSO® is currently priced below VYONDYS 53. Upon information and belief, if required to pay a royalty to Sarepta, the NS Counterclaimants may have to raise the price for VILTEPSO®, thereby reducing their ability to compete on price against Sarepta, which would necessarily reduce price competition in

the Product Market in the U.S. Higher prices in the Product Market as a result of Sarepta's conduct would harm consumers. Upon information and belief, if the NS Counterclaimants did not raise prices for VILTEPSO®, this would divert money and personnel from activities supporting the further development of VILTEPSO® and research and development of additional DMD treatments. This could deprive DMD patients of new safe and effective therapies.

110. For the same reasons, Sarepta's demand for monetary damages including a royalty in this lawsuit would also raise the NS Counterclaimants' costs, reduce their ability to compete, and harm competition. Thus, Sarepta's abuse of the legal process by asserting patents it knows were fraudulently obtained has harmed competition in the Product Market in the U.S. as well as the NS Counterclaimants.

111. The amount of antitrust injury the NS Counterclaimants have suffered and will continue to suffer will be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, the NS Counterclaimants pray for judgment against Defendant Sarepta, respectfully requests the following relief:

1. A judgment that the UWA Patents are invalid;

2. A judgment that the UWA Patents are unenforceable;

3. A judgment that this is an exceptional case and that Nippon Shinyaku be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

4. A judgment that Sarepta violated Section 2 of the Sherman Act, 15 U.S.C. § 2 and has injured the NS Counterclaimants;

5. An award of treble antitrust damages under Section 4 of the Clayton Act, 15. U.S.C. 15 U.S.C. § 14(a);

6. Permanently enjoining Sarepta from monopolizing or attempting to monopolize the relevant product and geographic markets, as provided by 15 U.S.C. § 26;

7. Costs and expenses in this action; and

8. Such other and further relief as the Court deems just and appropriate.

DEMAND FOR A JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(c), Nippon Shinyaku demands a jury trial on Claims II-IX and XI.

Dated: August 16, 2023

Respectfully submitted,

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